REMARKS

Claims 108, 109, 114-117, 120-123, and 128-144 were pending. Claims 139-144 have been canceled. Claims 108, 115, 116, 134, 136, and 137 have been amended.

Specifically, claim 108 has been amended to specify that the therapeutic composition comprises at least one "isolated" peptide which has "at least about 20% of the T cell epitopes of the protein allergen." Claim 108 has been further amended to specify that the peptide has the following characteristics: (1) a mean T cell stimulation index of at least about 3.5 determined in an *in vitro* T cell proliferation assay with T cells obtained from a population of humans sensitive to said allergen and (2) a positivity index of at least 150 as determined in an *in vitro* T cell proliferation assay with T cells obtained from a population of humans sensitive to said allergen. Support for the amendment of claim 108 can be found throughout the application, for example, in original claim 14 and at page 9, lines 24-33.

Claims 115 and 116 have been amended to delete the word "about."

Claim 134 has been amended to specify that the initial treatment of three to six dosages of the composition "once a week for 3-6 weeks." Support for the amendment of claim 134 can be found, for example, in original claim 36.

Claims 136 and 137 have been amended to provide proper antecedent basis.

The foregoing amendments should in no way be construed as an acquiescence to any of the Examiner's rejections and have been made solely to expedite examination of the present application. No new matter has been added. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Rejection of claims 108, 109, 114-117, 120-123, and 128-144 Under 35 U.S.C. §112, Second Paragraph

Claims 108, 109, 114-117, 120-123, and 128-144 are rejected under 35 U.S.C. §112, second paragraph, "as being indefinite." Claims 139-144 have been canceled. Therefore, this rejection is moot with regard to claims 139-144.

Claim 108

Claim 108 is considered indefinite based on the phrase "about 20% of the T cell epitopes recognized by T cell receptor." The Examiner states that "it is not clear whether this refers to

20% of the T cell receptors in the particular human being treated or to 20% of the T cell receptors of an aggregate of several individuals . . ."

Applicants respectfully traverse this rejection. However, to expedite prosecution, claim 108 has been amended to specify that the peptide comprises at least about 20% of the T cell epitopes of the protein allergen.

Claims 136 and 137

Claims 136 and 137 have been amended to provide proper antecedent basis.

Rejection of claims 108, 109, 114-117, 120-123, and 128-144 Under 35 U.S.C. §112, First Paragraph

Claims 108, 109, 114-117, 120-123, and 128-144 are rejected under 35 U.S.C. §112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention." Applicants respectfully traverse this rejection. However, to expedite prosecution, the claims have been amended as described below.

Claim 108

Claim 108 has been amended to specify that the peptide is "isolated."

Claims 115 and 117

Claims 115 and 117 have been amended to delete the word "about."

Claims 134

Claim 134 has been amended to specify administration "once a week."

Claims 139-144

Claims 139-144 have been canceled. Therefore, rejections pertaining to claims 139-144 are moot.

Rejection of claims 108, 109, 114-117, 120-123, and 128-133 Under 35 U.S.C. §103(a)

Claims 108, 109, 114-117, 120-123, and 128-144 are rejected under 35 U.S.C. §103(a) "as being unpatentable over Briner *et al.* (1993) PNAS 90:7608." Applicants respectfully traverse this rejection.

Briner *et al.* fail to teach or suggest the claimed methods which encompass the use of a peptide having the particular claimed combination of features. The present invention is based on the recognition that peptides which satisfy a combination of features, *e.g.*, at least 20% of the T cell epitopes of a protein allergen, a mean T cell stimulation index of at least about 3.5, and a positivity index of at least 150, find particular utility in human therapy. Nothing in the cited reference suggests that the particular combination of functional and technical characteristics now claimed finds particular utility in the treatment of humans.

Accordingly, the claimed invention resides in (1) the selection of a particular set of parameters which have unexpectedly been found to be useful indicators of therapeutic activity in humans; and (2) the elucidation of the values and/or ranges associated with therapeutic utility in humans for each of the selected parameters. The cited reference fails to teach or suggest either the selection of all the claimed the parameters or the elucidation of their values or ranges in therapeutic compositions for human treatment. Therefore, the claims as amended are patentable over Briner *et al.*

Rejection of claims 108, 114, 115, 120-123, 129, 131, and 133 Under 35 U.S.C. §102(b) or 102(e)

Claims 108, 114, 115, 120-123, 129, 131, and 133 are rejected under 35 U.S.C. §102(b) or 102(e) "as being anticipated by Rogers *et al.* (WO 93/08280 or U.S. 5,547,669), as evidenced by Briner *et al.* Applicants respectfully traverse this rejection.

Like Briner *et al.*, Rogers *et al.* fail to teach or suggest the claimed methods which encompass the use of a peptide having the particular claimed combination of features. As described above, the present invention is based on the recognition that peptides which satisfy a combination of features, *e.g.*, at least 20% of the T cell epitopes of a protein allergen, a mean T cell stimulation index of at least about 3.5, and a positivity index of at least 150, find particular utility in human therapy. Nothing in the cited reference suggests that the particular combination

of functional and technical characteristics now claimed finds particular utility in the treatment of humans. Based on at least the foregoing, claims 108, 114, 115, 120-123, 129, 131, and 133 are novel in view of the cited references.

Rejection of claims 108, 109, 114, 120-123, and 128-133 Under 35 U.S.C. §102(a)

Rejection of claims 108, 115-117, and 138 Under 35 U.S.C. §103(a)

Claims 108, 109, 114, 120-123, and 128-133 are rejected under 35 U.S.C. §102(a) "as being anticipated by Gefter *et al.* (WO 93/19178), in light of Briner *et al.* Claims 108, 115-117, and 138 are also rejected under 35 U.S.C. §103(a) "as being unpatentable over Gefter *et al.* (WO 93/19178).

As discussed above with regard to Briner *et al.* and Rogers *et al.*, the substance of which is reiterated here, Gefter *et al.* also fail to teach or suggest the claimed methods which encompass the use of a peptide having the particular claimed combination of features. Accordingly, claims 108, 109, 114, 120-123, and 128-133 are novel and patentable in view of the cited references.

Rejection of claims 108 and 136 Under 35 U.S.C. §103(a)

Claims 108 and 136 are rejected under 35 U.S.C. §103(a) "as being unpatentable over Briner *et al.* in view of Litwin *et al.*" Applicants respectfully traverse this rejection.

Litwin *et al.* fail to cure the deficiencies of Briner *et al.* which fail to teach or suggest the claimed methods encompassing the use of a peptide having the particular claimed combination of features (see arguments above regarding the rejection of claims 108, 109, 114-117, 120-123, and 128-144 are rejected under 35 U.S.C. §103(a) "as being unpatentable over Briner *et al.*). Accordingly, neither Briner *et al.* nor Litwin *et al.*, either alone or in combination, teaches or suggest the claimed combination of features. Therefore, claims 108 and 136 are patentable in view of the cited references.

Rejection of claims 108 and 136 Under 35 U.S.C. §103(a)

Claims 108 and 136 are rejected under 35 U.S.C. §103(a) "as being unpatentable over Rogers *et al.* in view of Litwin *et al.*"

As described immediately above, Litwin *et al.* fail to cure the deficiencies of Rogers *et al.* which fail to teach or suggest the claimed methods encompassing the use of a peptide having the particular claimed combination of features (see arguments above regarding the rejection of

claims 108, 114, 115, 120-123, 129, 131, and 133 under 35 U.S.C. §102(b) or 102(e) "as being anticipated by Rogers *et al.* (WO 93/08280 or U.S. 5,547,669), as evidenced by Briner *et al.*). Accordingly, neither Rogers *et al.* nor Litwin *et al.*, either alone or in combination, teaches or suggests the claimed combination of features. Therefore, claims 108 and 136 are patentable in view of the cited references.

Rejection of claims 108 and 136 Under 35 U.S.C. §103(a)

Claims 108 and 136 are rejected under 35 U.S.C. §103(a) "as being unpatentable over Gefter *et al.* in view of Litwin *et al.*"

As described immediately above, Litwin *et al.* fail to cure the deficiencies of Gefter *et al.* which fail to teach or suggest the claimed methods encompassing the use of a peptide having the particular claimed combination of features (see arguments above regarding the rejection of claims 108, 109, 114, 120-123, and 128-133 under 35 U.S.C. §102(a) "as being anticipated by Gefter *et al.* (WO 93/19178), in light of Briner *et al.*). Accordingly, neither Gefter *et al.* nor Litwin *et al.*, either alone or in combination, teaches or suggests the claimed combination of features. Therefore, claims 108 and 136 are patentable in view of the cited references.

Rejection of claims 108, 109, 115, 116, 120-123, and 128-133 Under 35 U.S.C. §12(f)

Claims 108, 109, 115, 116, 120-123, and 128-133 are rejected under 35 U.S.C. §102(f). Applicants respectfully traverse this rejection. The claimed invention resides in (1) the selection of a particular set of parameters which have unexpectedly been found to be useful indicators of therapeutic activity in humans; and (2) the elucidation of the values and/or ranges associated with therapeutic utility in humans for each of the selected parameters.

SUMMARY

If a telephone conversation with applicant's attorney would expedite the prosecution of the above-identified application, the examiner is urged to call applicant's attorney at (617) 227-7400.

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Respectfully submitted,

By _____

Jeanne M. DiGiorgio
Registration No.: 41,710
LAHIVE & COCKFIELD, LLP
28 State Street
Boston, Massachusetts 02109
(617) 227-7400
(617) 742-4214 (Fax)
Attorney/Agent For Applicant